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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,972	WILLMANN ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/16/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 17 and 18, filed on July 5, 2006, is acknowledged and has been entered. Claims 1-16 have been cancelled. Claims 19-32 have been added. Accordingly, claims 17-32 are pending. Claims 17-32 are under examination.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)), including the current status, i.e. abandoned or US Patent Number, of the prior application. In this case, the current status of ASN 09/787,092, i.e. abandoned, has not been updated. Additionally, the reference to prior applications is incomplete and lacks continuity in failing to state that ASN 09/787,092 which was filed on March 12, 2001, is a 371 National Stage application of PCT/US99/21731 which was filed on September 21, 1999, and which is a CIP of 09/158,406 which was filed on September 22, 1998, now US Patent 6,495,333.

Specification

3. The disclosure is objected to because of the following informalities:

The brief description of the drawings in the specification do not appear to coincide with the figures in the drawings which are designated by individual legends: Figure 2A to Figure 2J have not been individually and differentially described. Figure 3A to Figure 3I have not been individually and differentially described. Figure 4A to Figure 4K have not been individually and differentially described. Figure 6A to Figure 6C have not been individually and differentially described.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is ambiguous in being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, it is unclear what structural and functional cooperative relationship exists between each one of 1) the plurality of dendritic cell-distinguishing antibodies in step (b), 2) the at least one antibody specific for a dendritic cell surface marker in step (b), and 3) the at least one distinguishable DC subset in step (c). Step (c) recites "flow cytometrically assaying ... for the binding of the antibody specific for the dendritic cell surface activation marker",

but fails to define the intended purpose for the plurality of dendritic cell-distinguishing antibodies recited in step (b).

- Step (c) also lacks clear antecedent basis in reciting, "by at least one distinguishable DC subset" since it is unclear how it relates or what role it plays in the claimed method for measuring dendritic cell function. Should the "at least one distinguishable DC subset" be identified or bound by antibodies specific thereto? However, no such antibody appears to be recited in the claim.

- A correlation step is also lacking because it is unclear how "assaying for binding ... by at least one distinguishable DC subset" provides a measure of dendritic cell function as required by the preamble.

Claim 30 lacks antecedent basis in reciting, "said dendritic cell subsetting antibody". It is further unclear what Applicant intends to encompass in reciting, "subsetting antibody." It is especially unclear how the dendritic cell function is measured by at least one distinguishable dendritic cell subset. See also claims 31 and 32.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 17 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22 and 23 of U.S. Patent No. 6,495,333. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods recite a flow cytometric method for measuring dendritic cell function by 1) contacting the whole blood sample with a dendritic cell activator; 2) further contacting the activated cells with a cocktail of antibodies that bind dendritic cells to isolate the dendritic cells from other cells, antibodies that bind a subset portion of the dendritic cells, and at least one antibody that binds a dendritic cell surface marker indicative of activation, i.e. cytokine; then 3) flow cytometrically measuring binding of the at least one activation specific antibody to the dendritic cell surface marker in the dendritic cell that also is concurrently bound to the subsetting antibody; wherein the measure of the complex formed in step 4) provides a measure of dendritic cell function.

US Patent 6,495,333 is silent in reciting that the cytokine bound by the at least one cytokine specific antibody is a dendritic cell surface marker indicative of activation.

However, US Patent 6,495,333 provides that the cytokine antigen that is indicative of activation is any one of CD25, CD40, CD80, CD86, HLA-DR, and HLA-DQ (claim 23 of US Patent 6,495,333) which are the dendritic cell surface markers indicative of activation, that are recited by the instant application in claim 18.

6. Claims 17 and 19-32 are rejected on the ground of nonstatutory double patenting over claims 1 and 5-18 of U. S. Patent No. 6,495,333 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: in this case, the dendritic cell activators including lipopolysacchararide (LPS), phorbol 12-myristate 13 acetate plus ionomycin (PMA-I), and CD40-crosslinker recited in claims 19-22, the plurality of dendritic cell-distinguishing antibodies which are collectively specific for CD3, CD4, CD14, CD16, CD19, CD20, CD56, and HLA-DR labeled with FITC as identical fluorophore recited in claims 23-29, the dendritic cell subsetting antibodies such as CD11c and CD123 recited in claims 30-32, are disclosed throughout the specification of US Patent 6,495,333, as applied to both cell surface binding (see column 7, lines 32-51) and intracellular binding of cytokine specific antibodies in measuring dendritic cell function, and also recited in claims 1 and 5-18 of US Patent 6,495,333, as applied to intracellular binding of cytokine specific antibodies in measuring dendritic cell function.

Accordingly, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
August 2, 2006